



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,366	05/15/2006	Stephen Paul Collingwood	PR/4-33239A	9747

1095 7590 08/17/2010

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
EAST HANOVER, NJ 07936-1080

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
----------	--------------

1625

MAIL DATE	DELIVERY MODE
-----------	---------------

08/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,366	Applicant(s) COLLINGWOOD ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8, 9, 11, 16-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-9, 11, 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/27/10</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1625

DETAILED ACTION

1. Amendment and response filed by applicants dated May 27, 2010 have been entered and considered carefully.

Claims 4-7, 10, 12-15, 19 have been canceled. Claims 1-3, 8-9, 11, 16-18 are pending. Claims 20-22 stayed withdrawn from consideration per 37 CFR 1.142(b).

2. The rejection of claims 1-3, 11, 16-18 under 35 USC 112 second paragraph is dropped in view of the deletion of the confusing combination of L and M.

However, a survey of the specification provided the following:

On p.4-5, it was disclosed:

“Preferred compounds include those of formula I in salt or zwitterionic form where

R¹ and R³ are each independently a C3-Cl_s-carbocyclic group or a 5- to 12-membered heterocyclic group having at least one ring heteroatom selected from nitrogen, oxygen and sulphur;

R² is hydroxy;

L and M are (a bond and -CH₂-CH₂-), (-CH₂- and -CH₂-CH₂-) or (-CH~CH₂- and -CH₂-)

respectively and J is C1-C2-alkylene,

or L and M are (-CH₂- and -CH₂-CH₂-) or (-CH₂-CH₂- and -CH₂-) respectively and J is a bond;

R⁴ is C1-C4-alkyl;

R⁵ is C1-alkyl substituted by -CO-R⁶ or -CO-NH-R⁶.

or R⁵ is C2-Clo-alkyl substituted by -O-R₆, -S-R₆, -O-CO-R₆ or -R₆,

or R⁵ is C2-Cl₀-alkenyl or C2-Cl₀-alkynyl optionally substituted by -RS;

R₆ is a C3-C15-carbocyclic group,

or R⁶ is C1-Cl₀-alkyl optionally substituted by C1-Cl₀-alkoxy, O-R⁸ or a C3-C15-carbocyclic group; and

R⁸ is a C3-Cl_s-carbocyclic group.

Art Unit: 1625

Especially preferred compounds include those of formula I in salt or zwitterionic form where

R¹ and R³ are each independently a C3-C10-carbocyclic group, preferably phenyl, or a 5- to 9-membered heterocyclic group having at least one ring heteroatom selected from nitrogen, oxygen and sulphur, preferably thienyl;

R² is hydroxy;

L and M are (a bond and -CH₂-CH₂-), (-CH₂- and -CH₂-CH₂-) or (-CH₂-CH₂- and -CH₂-) respectively and J is C1-C2-alkylene, or L and M are (-CH₂- and -CH₂-CH₂-) or (-CH₂-CH₂- and -CH₂-) respectively and J is a bond;

R⁴ is C1-C4-alkyl;

R⁵ is C1 alkyl substituted by -CO-R⁶ or -CO-NH-R⁷;

or R⁵ is C2-C5-alkyl substituted by -O-R⁶, -S-R⁶, -O-CO-R⁶ or -R⁸;

or R⁵ is C2-C4-alkenyl or C2-C5-alkynyl optionally substituted by -RS;

R⁶ is a C3-C10-carbocyclic group, preferably phenyl,

or R⁶ is C1-C15-alkyl optionally substituted by C1-C4-alkoxy, O-R⁶ or a C3-C10-carbocyclic group; and

R⁸ is a C5-C10-carbocyclic group, preferably phenyl.”

From the above preferred embodiment, no antecedent basis for the instant amended scope was found. Nowhere was the description that L is bond, M is CH₂-CH₂, J is C1-2alkylene. Please note that in addition to the lacking of descriptive support for the amended scope, it was further observed that all the *pyrrolidinyl* compounds of table 2 or 4 have J=CH₂, i.e. not corresponding to the instant amended scope. The instant amended scope thus is NEW MATTER. This is a new matter rejection and removal of all new matter is required. In re Russmussen 210 USPQ 325.

3. The rejection of claims 1-3, 11, 16-18 under 35 USC 112 first is maintained for reason of record. The instantly amended scope does not corresponding to the scope of enablement in the specification as delineated in the previous office action.

Art Unit: 1625

Applicants argued that there are sufficient information about the invention which is not persuasive. The survey delineated supra in section 2 is hereby incorporated by reference which clearly indicated the lacking of description of the "amended scope" and the exclusive description to J=CH₂ compounds.

4. The rejections of claims 1-3, 11, 16-18 under 35 USC 102(f) or (g) or (e) over US 7,399,861 or Pratt et al. '094 are dropped in view of the amendment that J cannot be bond.

5. The rejection of claims 1-3, 8-9, 11, 16-18 under 35 USC 103(a) over WO03/087094 in view of Ogino et al. US 6,846,835 is maintained for reason of record.

The gist of applicants' argument is that each reference differ from the instant claims. Please note that if references disclosed identical/same invention as the claims, the reference would be anticipatory instead of obvious. Please note that it is the combination of analogous art which provided teaching, suggestion and modification of the prior art compounds with attributes of modification that resulted in the instant claims. Both WO03/087094 and Ogino '835 are analogous art (see MPEP 2141.01(a)). It is improper for applicants to argue the difference of each reference individually when the rejection is made with the *combination* of the teaching with explicit delineation of the teaching, suggestion and modification using the combination attributes of the analogous art. Applicants merely argued that the references and the claims are *different* and failed to provided any factual support that the instant claims are unexpected. In re Keller 205 USPQ 871.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1625

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
July 29, 2010

/Celia Chang/
Primary Examiner
Art Unit 1625